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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/764,445

01/19/2001

Edward W. Merrill

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EXAMINER

BERMAN, SUSAN W

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

05/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/764,445	Applicant(s) MERRILL ET AL.	
	Examiner /Susan W. Berman/	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-130 and 143-149 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124-130, 143-149 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4-16-09, 10-29-04</u> . | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04-16-2009 has been entered.

Response to Arguments

The rejection of claims under 35 USC 112, second paragraph, is withdrawn.

Response to Arguments

Applicant's arguments filed 04-16-2009 have been fully considered but they are not persuasive with respect to the following issues.

With respect to inherent functions or properties in a disclosure the relevant passage referred to in MPEP is "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient". The examiner cannot "understand" or "assume inherency", as argued by applicant, for a claimed process that has not been described within the instant disclosure. No extrinsic evidence has been made of record in the instant case to support inherency for the instant descriptive matter that supports recitations in the instant claims that have not been found to have been disclosed in the instant disclosure.

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The dictates of MPEP 2163.07 and 2164 have been considered, as requested by applicant. Example 6 on pages 44- discloses heating a sample to 175⁰C, holding the temperature for 300 followed by irradiation using a van de Graaff generator. The description on page 45 is that the electron beam “entered the chamber through the thin foil at top and hit the surface with the hemispheric hole. The dose received by the specimen was such that a maximum dose of 20 Mrad was received approximately 5 mm below the surface of the polymer being hit by electrons.” After irradiation the heating was stopped and the specimen cooled to room temperature. There is no mention of a conveyor belt, cycles of radiation, heating to melt after passages through a conveyor belt. There is nothing to indicate that specimens were taken out of the belt and reintroduced to continue an irradiation process. There is no disclosure that irradiation is performed while the specimen is moving on a belt instead of being irradiated in place through the thin foil at top of the chamber. There is even less evidence that the specimens were taken out of a belt and melted when reintroduced to the belt to continue irradiation and heating. Applicant has not provided any extrinsic evidence to support the argument that steps are inherently disclosed in the specification by mention of use of a van de Graaff generator to irradiate UHMWPE.

With regard to applicant’s comments, it is agreed that the phrases “subsequent melting” and “remelting” both have the meaning heating above the melting temperature after an initial melting and irradiation. None of the instant claims recites “subsequent melting”. The instant claims recite irradiating UHMWPE and heating the irradiated article to 150⁰C or above (temperatures above the melting point). There is no recitation of a first step of melting UHMWPE before the step of irradiation and the step of heating at 150⁰C or above or of

following the recited heating step with another irradiation step and another heating step before cooling and forming a medical implant.

With respect to the effective date of invention, applicant clearly states in the Declaration under § 1.131 of Edward Merrill filed 06-20-2007 that methods comprising irradiation followed by “subsequent melting” were disclosed in Application Serial No 08/726,313, filed 10-02-1996 and in Application Serial No. 08/798,638, filed 02-11-1997. See section 10, page 5 of the Declaration.

The data in the Declaration under § 1.131 of Edward Merrill filed 06-20-2007 and discussed in applicant’s remarks has been reconsidered. It is agreed that Experiment 2 in Exhibit 3 shows a sequence of heating and irradiating a sample to achieve a total radiation dose (50 Mrad). The Experiment is titled “Irradiation of barstock while amelt”. Experiment 2 does not include a heating/melting step after (subsequent to) the final irradiation dose of 50 MRad. The data does show that the sample was reheated after each irradiation pass in order to keep the sample in the melt when irradiated. The heating between irradiation doses is performed to keep the sample in the melt when irradiated. There is no “subsequent melting” step following the irradiation dose of 50 MRad. Thus the sample is considered to exemplify irradiation in the melt, i.e. the “MIR” process disclosed in the instant specification. The specification has been considered in its entirety, especially with respect to the disclosure of method steps employed in "MIR" process and the disclosure of distinctly different method steps in the “IR-SM” processes.

Claim Interpretation and Effective Filing Date

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Claims 124-130 and 143-149, as amended, recite the irradiation and subsequent melting method (“IR-SM”) first disclosed in SN 08/726,313, filed 10-02-1996. Thus, claims 124-130 and 143-149, wherein the irradiation step precedes the melting step have an effective filing date of 10/02/1996 with respect to prior art disclosures. The instant claims are considered to be fully supported by the disclosure of SN 08/726,313, but not by SN 08/600744 filed 02-13-1996, wherein a method of irradiating UHMWPE in the molten state is disclosed but subsequent melting after irradiation is not taught. Therefore, the earliest effective filing date of the instant claims wherein the method steps comprise irradiation followed by melting the irradiated UHMWPE is considered to be the 10/02/1996 filing date of SN 08/726,313.

Furthermore, claims 128-129 are not supported by the disclosure of SN 08/600,744 because SN ‘744 does not disclose the swell ratio or degree of oxidation of the crosslinked UHMWPE. Thus claims 128-129 are not entitled to the 02-13-1996 filing date of SN ‘744. SN ‘313 does disclose the swell ratio or degree of oxidation of the disclosed UHMWPE, therefore, the effective filing date for claims 128-129 is considered to be 10/02/1996.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 124-130 and 143-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Shen et al (6,228,900, having an effective filing date of 07/09/1996). Applicant's effective filing date for a process comprising irradiation followed by melting the irradiated UHMWPE is 10/02/1996 (effective filing date of SN 08/726313). Shen et al disclose a process for preparing a medical implant comprising irradiating an UHMWPE article followed by thermal treatment by remelting and cooling, fabricating an implant and sterilizing. See column 4, lines 8-18 and 46-51, column 5, lines 29-52, column 7, lines 20-31, column 7, line 53, to column 8, line 9, column 8, lines 34-64, Example 1 and Figures 4 and 5. Since the process steps set forth in the instant claims are disclosed by Shen et al, the products resulting therefrom would be expected to have the same properties as the medical implants set forth in instant claims 126-129.

Claims 125-129 and 147-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyon et al (6,168,626, having an effective filing date of 05/06/1996). Hyon et al disclose UHMWPE molded articles for artificial joints prepared by irradiating an UHMWPE molded article and subsequently heating to the compression-deformation temperature, a temperature not less than the melting point. The treated UHMWPE is cooled and processed to provide a socket for artificial joints. See column 3, line 16, to column 5, line 13. With respect to claim 126 and 127, the products disclosed by Hyon et al would be expected to have the same properties as the instantly claimed products. The reasons are that Hyon et al disclose the process steps set forth in claim 125 and 128 and the process steps in claim 124 except for sterilizing the implant and that the properties of the product would be expected to be determined by the irradiation and compression-deformation melting steps.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-126 and 128-133 of copending Application No. 10/948440. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same method steps, i.e. melting and irradiating polyethylene, are set forth in the claims of '440 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '440. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '440 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 126-127 and 135-136 of copending Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the polyethylene, are set forth in the claims of '209 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '209. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '209 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 127-129 of copending Application No. 10/696362. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the UHMWPE are set forth in the claims of '362 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '362 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-129 of copending Application No. 10/901089. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the heated UHMWPE are set forth in the claims of '089 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '089 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 126-129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124,125,129,130,132-134,136, 138, and 145-152 of copending Application No. 10/197263. Although the conflicting claims are not identical, they are not patentably distinct from each other because the fabricated articles set forth in the claims of '263 are produced by irradiating and melting UHMWPE, as are the products set forth in the instant claims. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
5/17/2009

/Susan W Berman/
Primary Examiner
Art Unit 1796